



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0747]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0575. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles--21 CFR 514.1(b)(7) and (b)(8) (OMB Control Number 0910-0575)--Extension

The Center for Veterinary Medicine has written this guidance to address a perceived need for Agency guidance in its work with the animal health industry. This guidance describes the procedures that the Agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act of 1988 (Public Law 100-670) permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and

Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision. The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: "USP definition" approach or "Dosage adjusted" approach. The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the above data is records of generic drug applications over the past 10 years.

In the Federal Register of October 24, 2011 (76 FR 65733), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which, however, did not address the questions posed in 60-day notice regarding the collection of information. The comment supported the bioequivalence program but suggested a revision to the determination of bioequivalence, which relates to the substance of the scientific recommendations in the guidance document. Under FDA's good guidance practices regulations

(21 CFR 10.115(f)(4)), the public may suggest at anytime that FDA revise a guidance document and under 21 CFR 10.115(g)(5), FDA will revise guidance documents in response to comments when appropriate.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden for Water Soluble Powders¹

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Same formulation/ manufacturing process approach	1	1	1	5	5
Same API/ solubility approach	5	5	5	10	50
Total burden hours					55

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Reporting Burden for Type A Medicated Articles¹

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Same formulation/ manufacturing process approach	2	2	2	5	10
Same API/ solubility approach	10	10	10	20	200
Total burden hours					210

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.